METHOD FOR EFFECTING HEMOSTASIS

Field of the Invention

(01) The present invention relates to a method for local management of bleeding wounds and, more particularly, a method for rapidly controlling bleeding even in patients receiving hemodialysis and anticoagulation treatments.

Background of the Invention

(02) During catheterization procedures, the nurse or physician will create an opening into an artery or other vessel with a conventional catheter introducer or dilator. Additionally, the catheter is often twisted or otherwise manipulated as it is advanced to the treatment site, thereby causing a further enlargement of the incision or puncture in the body of the patient.

(03) When the medical procedure is completed and the catheter is removed from the artery or other blood vessel, conventional practice has been to apply external pressure to the entry site until hemostasis occurs. Because many of the patients undergoing these procedures have been medicated with an anticoagulant such as heparin, the nurse may be required to apply external pressure to the incision site for an extended period of time period. The time period required to stop bleeding at the incision is not an efficient use of the nurses time period and a painful hematoma or unsightly bruise may still occur at the incision site because the artery will continue to bleed internally until clotting blocks the opening in the artery.

(04) What is desired therefore is a simple, safe and relatively inexpensive method for managing bleeding wounds such as lacerations, abrasions, nose bleeds, vascular access sites, percutaneous catherters, or tubes and surgical debridement. Preferably, the method will provide a rapid control of bleeding even in patients receiving hemodialysis and anticoagulation treatments.

Summary of the Invention

(05) The present invention provides a method for effecting hemostasis at a puncture wound extending to a blood vessel. The puncture wound may, or may not, have an introducer or catheter disposed therein. The method includes applying pressure proximal to the puncture wound, and directing a cationic application surface of a closure pad against the puncture wound with force sufficient to prevent fluid from exiting the puncture wound, by collapsing the blood vessel. The pressure proximal to the puncture wound is then removed. If an introducer or catheter is present, it is then removed from the puncture wound. The method then includes maintaining the force on the closure pad against the wound for at least a first predetermined time period. Upon verification (usually visually) of hemostasis, the force to the pad is removed. Dressing may be applied over the closure pad and the puncture wound. The dressing and the closure pad will then be removed after a second predetermined time period.

(06) According to one aspect of the present invention, the application surface of the pad is a biopolymer of glucosamine, including but not limited to poly-N-acetylglucosamine. In some forms of the invention, the application surface is an acetate salt of a biopolymer of glucosamine.

(07) According to further aspect of the present invention, when an introducer or catheter is disposed in the wound, the first predetermined time period is substantially proportional to the diameter of the introducer or the catheter. According to another aspect, the first predetermined time period is equal to about ten minutes. According to an additional aspect, the second predetermined time period is equal to about twenty-four hours.

(08) The method of the present invention provides many benefits, including reducing the time period required to stop bleeding at a puncture wound and decreasing the likelihood that a hematoma will form particularly, but not limited to, cases following removal of an introducer or a catheter from the puncture wound. These and other features and benefits of the present disclosure will become more apparent upon reading the following specification in combination with the accompanying drawing figures.

Brief Description of the Drawings

(09) Fig. 1 is a side elevation view, partially in section, showing a catheter extending through a puncture wound into an artery of a patient, with the puncture wound extending through an epidermal and dermal layer of the patient's skin and through a wall of the artery;

(10) Fig. 2 is a side elevation view, partially in section, showing the catheter removed from the puncture wound and a closure pad secured to the patient's skin over the puncture wound in accordance with a method of the present invention for effecting hemostasis;

(11) Fig. 3 is a side elevation view, partially in section, showing the closure pad secured to the patient's skin over the puncture wound in accordance with the present invention, and hemostasis occurring within the puncture wound; and

(12) Fig. 4 is a flow chart illustrating the method of the present invention for effecting hemostasis in a puncture wound.

(13) Like reference characters designate identical or corresponding components and units throughout the several views.

Detailed Description of the Preferred Embodiments

(14) The present invention is described hereinafter with specific reference to the use of the present invention for sealing an incision or puncture wound leading to a blood vessel in a patient. It is contemplated that the present invention may be used with nearly any catheterization or other medical procedure such as laparoscopic or other minimally or less invasive surgeries wherein it is desirable to seal an incision or puncture wound in the patient to prevent the loss of the patient's body fluid therethrough.

(15) In order to more fully understand and appreciate the present invention, a brief description of a conventional angiographic catheterization procedure through a femoral artery 10 of a patient is set forth herein and illustrated in Figs. 1 through 3, for purposes of illustration. In such a procedure, an angiographic needle (not shown) is inserted percutaneously through the epidermal and dermal layer of the skin 12 of the patient at an angle to form an incision or

puncture wound 14. The needle is inserted percutaneously into the skin 12 until the needle pierces the wall of the femoral artery 10. The puncture of the artery 10 by the needle is then confirmed by the physician and a small diameter guide wire (not shown) is inserted through a central lumen in the needle and the needle is withdrawn over the guide wire while pressure is applied to the artery 10 to limit the bleeding and prevent the formation of a hematoma at the incision site. The catheter 16 and an outer introducer or catheter sheath (not shown) are inserted over the guide wire. Next, the catheter 16 is advanced to the final location and the procedure is performed. Once the procedure has been completed, the catheter 16 is removed and a method according to the present invention for controlling bleeding from the puncture wound 14 is conducted as described hereinafter.

(16) Referring also to Fig. 4, the method includes applying pressure proximal to the puncture wound 14 to at least partially collapse the blood vessel 10, as shown at "A", and directing a cationic biopolymer of glucosamine application surface of a closure pad 18 against the puncture wound 14 with force sufficient to substantially prevent fluid from exiting the puncture wound 14, as shown at "B". Then the pressure proximal to the puncture wound 14 is removed, as shown at "C", and the catheter 16 is removed from the puncture wound 14, as shown at "D". The method then includes maintaining the force on the closure pad 18 and against the wound 14 for at least a first predetermined time period, as shown at "E", and removing the force on the closure pad, as shown at "G", if hemostasis is verified, as shown at "F". Hemostasis is generally verified visually.

(17) A dressing (not shown), can also be applied over the closure pad 18 and the puncture wound 14, as shown at "H". The dressing and the closure pad 18 are then removed after a second predetermined time period, as shown at "I".

(18) Preferably, the application surface of, and in some forms of the invention, the entire closure pad 18, are preferably made substantially only of a cationic biopolymer of glucosamine provided in one or more of the following forms: poly-D-glucosamine; an acetate salt of poly-N-acetylglucosamine; an acetate salt of poly-D-glucosamine; poly-N-acetylglucosamine and poly-D-glucosamine; an acetate salt of poly-N-acetylglucosamine and poly-D-glucosamine; an acetate salt of poly-N-acetylglucosamine and an acetate salt of poly-D-

glucosamine; and poly-N-acetylglucosamine and an acetate salt of poly-D-glucosamine. In forms including an acetate salt, the application surface is water soluble. Acidic environments other than an acetate salt, such as lactic acid, can also be incorporated as part of the biopolymer of glucosamine.

(19) A cationic biopolymer of glucosamine is derived from chitosan, which is a collective term applied to deacetylated chitins in various stages of deacetylation and depolymerization. Chitin is the structural polymer of the exo-skeleton of arthropods and cell walls of fungi, and is composed of poly-N-Acetyl glucosamine units. These are linked by Beta 1-4 glycosidic bonds into a linear polymer containing 2,000 to 3,000 units.

(20) Chitosan is a derivative of solid waste from shell fish processing and can be extracted from fungus culture. Chitin is generally isolated and purified by first dissolving away the inorganic material, calcium carbonate, by treatment with hydrochloric acid. After the protein material is removed by digestion with hot diluted alkali, the chitin is bleached with permanganate followed by treatment with oxalic acid. Partial deacetylization of chitin by treatment with concentrated alkali solution at 130 to 150 degrees centigrade yields products which are soluble in dilute acetic acid.

(21) A common method to convert crab shell to Chitosan, for example, is as follows: The calcium carbonate is removed by immersing the shell in cold dilute hydrochloric acid, two to three hours are allowed for the reaction. The shell is then thoroughly rinsed with water. Protein is removed by treating the shell with caustic soda (3% strength). The shell is cooked in a 3% sodium hydroxide solution for a period of two hours at a temperature of 100° C and at atmospheric pressure. The remains are rinsed thoroughly with water to remove all traces of sodium hydroxide and protein, and bleached with potassium permanganate solution and again rinsed with water. The remains are then treated with oxalic acid to remove the permanganate solution, and then treated with a 40% caustic soda solution at 150° C to partially deacetylate the chitosan. This results in the formation of chitosan. By varying the amount of deacetylation, various viscosities of chitosan can be produced. The final pH of the chitosan solution is in the range of 4-5. It is possible to utilize chitosan in the following applications in various pH's and viscosities. However, the ideal mode is a solution of 2 grams of chitosan per liter of acetic acid

solution. This process is discussed in U.S. Patent No. 4,394,373 to Malette et al., which is incorporated herein by reference.

(22) If only the application surface of the closure pad 18 is made of a cationic biopolymer of glucosamine, then the remainder of the closure pad 18 can be made of a material that supports and/or supplements the application surface. The remainder of the closure pad 18 can, for example, comprise absorbent or non-absorbent material, and a rigid, semi-rigid or soft material. The remainder of the closure pad 18 can, for example, comprise a plastic, a cellulose polymer, or other suitable material.

(23) In addition, the application surface of, and in some forms of the invention, the entire closure pad 18, is soft and made of non-woven fibers. However, the application surface and/or the entire closure pad 18, can be made of woven material, layers of woven material, and woven and non-woven layers.

(24) Prior to use, the closure pad 18 is packed in a pouch (for example, made of foil, paper or Tyvek® material) and sterilized (for example, by E-beam radiation, ethylene oxide, or other suitable sterilization method, to a 10^{-6} sterility assurance level).

(25) The first predetermined time period is substantially proportional to a diameter of the catheter 16 (or of a diameter of an introducer for the catheter, if the introducer is used), and thus the resulting puncture wound 14. In general, however, the first predetermined time period is preferably equal to about ten minutes, although other time periods can be used. In any event, the pressure is not removed from the closure pad 18 and the puncture wound 14 until hemostasis is confirmed. Thus force may need to be maintained on the closure pad 18 for longer than ten minutes. The dressing can comprise gauze pads and tape, or other suitable dressings, placed over the closure pad.

(26) The second predetermined time period is preferably equal to about twenty-four hours. After twenty-four hours, the dressing and the closure pad 18 are removed from the puncture wound. If hemostasis can not be confirmed after removal of the dressing and the closure pad, a new closure pad and dressing should be applied to the wound, until hemostasis is confirmed.

(27) The method of the present invention provides many benefits, including reducing the time period required to stop bleeding at a puncture wound and decreasing the likelihood that a hematoma will form after removal of a catheter from the puncture wound. Modification to above-described preferred embodiment of the presently disclosed invention may become apparent to those skilled in the art. The scope of the invention is therefore intended to be limited solely by the scope of the appended claims.